UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

MAR 07 1991

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,621,638 issued November 11, 1986, was filed on February 22, 1991, under 35 U.S.C. 156.

The assistance of your Office is requested in determining whether the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC § 156(g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC § 156(d)(2)(A).

Our review of the application indicates that the product was not approved under section 515, but instead received permission to market under section 510(k) of the FFDCA. Accordingly, the subject patent may not be eligible for extension of the patent term under 35 USC § 156.

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Programs Administrator
Office of the Assistant Commissioner for Patents

cc: John L. LaPierre
Pfizer Inc.
Patent Department, 20th Floor
235 East 42nd Street
New York, NY 10017-5755